

This listing of claims replaces all prior versions and listings of claims in this application:

In the claims:

Claim 1 (currently amended): An isolated monoclonal anti-idiotypic antibody 11D10 produced by hybridoma cell line ATCC No. HB 12020 ~~or progeny thereof~~.

Claim 2 (original): The antibody of claim 1, further comprising a label capable of producing a detectable signal.

Claim 3 (currently amended): A hybridoma cell line designated ATCC No. HB 12020 ~~or progeny thereof~~.

Claim 4 (previously presented): A purified antibody having all the identifying characteristics of antibody produced by a hybridoma cell line according to claim 3.

Claim 5 (original): A hybridoma having all the identifying characteristics of a cell of the hybridoma cell line according to claim 3.

Claim 6 (withdrawn): An isolated polynucleotide comprising a sequence encoding a polypeptide having immunological activity of monoclonal anti-idiotypic antibody 11D10, wherein the polypeptide comprises at least 5 contiguous amino acids of a variable region of 11D10.

Claim 7 (withdrawn): A polynucleotide according to claim 6, wherein the variable region is from a light chain.

Claim 8 (withdrawn): A polynucleotide according to claim 6, wherein the variable region is from a heavy chain.

Claim 9 (withdrawn): The isolated polynucleotide of claim 6, wherein the 5 contiguous amino acids are depicted within SEQ ID NO:2.

Claim 10 (withdrawn): The isolated polynucleotide of claim 6, wherein the 5 contiguous amino acids are depicted within SEQ ID NO:4.

Claim 11 (withdrawn): The isolated polynucleotide of claim 6, wherein the encoding sequence is depicted within SEQ ID NO:1.

Claim 12 (withdrawn): The isolated polynucleotide of claim 6, wherein the encoding sequence is depicted within SEQ ID NO:3.

Claim 13 (withdrawn): An isolated polynucleotide according to claim 6, wherein the polynucleotide encodes at least 5 contiguous amino acids of a complementarity defining region.

Claim 14 (withdrawn): An isolated polynucleotide comprising a region of at least 15 contiguous nucleotides, said region capable of forming a stable duplex with a polynucleotide consisting of light chain variable encoding sequence of SEQ ID NO:1 under conditions where the region does not form a stable hybrid with SEQ ID NO:5 through SEQ ID NO:14.

Claim 15 (withdrawn): An isolated polynucleotide comprising a region of at least 15 contiguous nucleotides, said region capable of forming a stable duplex with a polynucleotide consisting of heavy chain variable encoding sequence of SEQ ID NO:3 under conditions where the region does not form a stable hybrid with SEQ ID NO:15 through SEQ ID NO:32.

Claim 16 (withdrawn): A polynucleotide according to claim 6, wherein the polynucleotide is a cloning vector.

Claim 17 (withdrawn): A polynucleotide according to claim 6, wherein the polynucleotide is an expression vector.

Claim 18 (withdrawn): The expression vector of claim 17, wherein the expression vector is vaccinia.

Claim 19 (withdrawn): A host cell comprising the polynucleotide of claim 6.

Claim 20 (currently amended): A polypeptide having immunological activity of anti-idiotypic antibody 11D10, wherein the polypeptide comprises an immunoglobulin variable region containing three light chain complementarity determining regions (CDRs) of antibody 11D10, and an immunoglobulin variable region containing three heavy chain CDRs of antibody 11D10, wherein the light chain variable region amino acid sequence is contained in an antibody produced by a hybridoma cell line designated ATCC NO. HB 12020 ~~or progeny thereof~~, and wherein the heavy chain variable region amino acid sequence is contained in an antibody produced by a hybridoma cell line designated ATCC NO. HB 12020 ~~or progeny thereof~~, and wherein the immunological activity of the polypeptide is an ability to stimulate a specific immune response against human milk fat globule (HMFG).

Claims 21-22 (canceled)

Claim 23 (previously presented): The polypeptide of claim 20, wherein the light chain variable region amino acid sequence is contained in SEQ ID NO:2 and the heavy chain variable region amino acid sequence is contained in SEQ ID NO:4.

Claims 24-25 (canceled)

Claim 26 (previously presented): The polypeptide of claim 20, wherein the polypeptide contains a sequence of at least 2 contiguous amino acids which are identical in forward or reverse orientation to 2 contiguous amino acids of a sequence in human mucin from human milk fat globule (HMFG), wherein said HMFG sequence is contained in SEQ ID NO:33.

Claim 27 (original): A fusion polypeptide comprising the polypeptide of claim 20.

Claim 28 (previously presented): The fusion polypeptide of claim 27 further comprising a cytokine.

Claim 29 (previously presented): The fusion polypeptide of claim 28, wherein the cytokine is granulocyte macrophage colony stimulating factor.

Claim 30 (previously presented): The fusion polypeptide of claim 28, wherein the cytokine is interleukin 2.

Claim 31 (canceled)

Claim 32 (currently amended): The fusion polypeptide of claim ~~[[31]]~~ 27, wherein the three CDRs from the light chain variable region of 11D10 and the three CDRs from the heavy chain variable region of 11D10 are linked by a linker polypeptide of about 5 to 20 amino acids.

Claim 33 (previously presented): The fusion polypeptide of claim 27, comprising the light chain variable region and the heavy chain variable region of antibody 11D10, wherein the light chain variable region and the heavy chain variable region are contained in SEQ ID NO:2 and SEQ ID NO:4, respectively.

Claim 34 (previously presented): The fusion polypeptide of claim 27 further comprising a heterologous immunoglobulin constant region.

Claim 35 (currently amended): A humanized antibody comprising three CDRs from the light chain variable region of 11D10, three CDRs from the heavy chain variable region of 11D10, and a constant region that is a human sequence, wherein the humanized antibody is able to stimulate a specific immune response against human milk fat globule (HMFG), wherein the light chain variable region amino acid sequence is contained in an antibody produced by a hybridoma cell line designated ATCC No. HB 12020 ~~or progeny thereof~~, and wherein the heavy chain variable region amino acid sequence is contained in an antibody produced by a hybridoma cell line designated ATCC No. HB 12020 ~~or progeny thereof~~.

Claim 36 (original): A polymeric 11D10 polypeptide comprising a plurality of the polypeptide of claim 20.

Claim 37 (previously presented): A composition comprising anti-idiotypic antibody 11D10 of claim 1 and a pharmaceutically acceptable excipient.

Claim 38 (withdrawn): A pharmaceutical composition comprising an effective amount of the polynucleotide of claim 6 and a pharmaceutically acceptable excipient.

Claim 39 (currently amended): A composition comprising a pharmaceutically acceptable excipient and a polypeptide having immunological activity of anti-idiotypic antibody 11D10, wherein the polypeptide comprises an immunoglobulin variable region containing three light chain complementarity determining regions (CDRs) of antibody 11D10, and an immunoglobulin variable region containing three heavy chain CDRs of antibody 11D10, wherein the light chain variable region amino acid sequence is contained in an antibody produced by a hybridoma cell line designated ATCC NO. HB 12020 ~~or progeny thereof~~, and wherein the heavy chain variable region amino acid sequence is contained in an antibody produced by a hybridoma cell line designated ATCC NO. HB 12020 ~~or progeny thereof~~, and wherein the immunological activity of the polypeptide is an ability to stimulate a specific immune response against human milk fat globule (HMFG).

Claim 40 (previously presented): An immunogenic composition comprising anti-idiotypic antibody 11D10 of claim 1 and a pharmaceutically acceptable excipient.

Claim 41 (withdrawn): A vaccine comprising an effective amount of the polynucleotide of claim 6 and a pharmaceutically acceptable excipient.

Claim 42 (previously presented): An immunogenic composition comprising the polypeptide of claim 20 and a pharmaceutically acceptable excipient.

Claim 43 (previously presented): The immunogenic composition of claim 40, further comprising an adjuvant.

Claim 44 (withdrawn): The vaccine of claim 38, wherein the vaccine is a live virus or viral expression vector.

Claim 45 (withdrawn): The vaccine of claim 44, wherein the vaccine is vaccinia.

Claim 46 (withdrawn): A method of eliciting an immune response in an individual with advanced human milk fat globule associated disease comprising the step of administering an effective amount of monoclonal anti-idiotypic antibody 11D10 of claim 1 to the individual.

Claim 47 (withdrawn): A method of eliciting an immune response in an individual with advanced human milk fat globule associated disease comprising the step of administering an effective amount of the vaccine of claim 43 to the individual.

Claim 48 (withdrawn): The method of claim 46, wherein the advanced human milk fat globule associated disease is breast cancer.

Claim 49 (withdrawn): A method for removing a labeled anti-human milk fat globule (HMFG) antibody from an individual who has received a labeled anti-HMFG antibody, comprising administering monoclonal antibody 11D10 of claim 1 to the individual.

Claim 50 (withdrawn): A method for detecting the presence of an anti-human milk fat globule (HMFG) antibody bound to a tumor cell comprising the steps of contacting the tumor cell with monoclonal antibody 11D10 of claim 1 for a sufficient time to allow binding to the anti-HMFG antibody, and detecting the presence of any 11D10 which is bound to the anti-HMFG antibody.

Claim 51 (withdrawn): A method for detecting an anti-human milk fat globule immunological response in an individual comprising the steps of (a) contacting a biological sample from the individual with the monoclonal antibody 11D10 of claim 1 under conditions that permit formation of a stable complex between monoclonal antibody 11D10 and an antibody that binds to 11D10; and (b) detecting any stable complexes formed.

Claim 52 (withdrawn): A method of detecting in a sample an antibody that binds to monoclonal antibody 11D10 comprising the steps of: (a) contacting antibody from a sample obtained from the individual with the polypeptide of claim 20 under conditions that permit the formation of a stable antigen-antibody complex; and (b) detecting the stable complex formed in step (a), if any.

Claim 53 (canceled)

Claim 54 (previously presented): A kit comprising anti-idiotypic antibody 11D10 of claim 1 in suitable packaging.

Claim 55 (original): The kit of claim 54, wherein the 11D10 comprises a detectable label.

Claim 56 (previously presented): A kit comprising the polypeptide of claim 20 in suitable packaging.

Claim 57 (withdrawn): A kit for detection or quantitation of a polynucleotide comprising a polynucleotide encoding a variable region of monoclonal antibody 11D10 or a portion thereof, said kit comprising the polynucleotide of claim 14 in suitable packaging.

Claim 58 (withdrawn): A kit for detection or quantitation of a polynucleotide comprising a polynucleotide encoding a variable region of monoclonal antibody 11D10 or a portion thereof, said kit comprising the polynucleotide of claim 15 in suitable packaging.

Claim 59 (previously presented): A composition comprising an effective amount of anti-idiotypic antibody of claim 1, wherein an effective amount is an amount sufficient to elicit an anti-human milk fat globule immune response.

Claim 60 (previously presented): A composition comprising an effective amount of the antibody of claim 4, wherein an effective amount is an amount sufficient to elicit an anti-human milk fat globule immune response.

Claim 61 (previously presented): A composition comprising an effective amount of the polypeptide of claim 20, wherein an effective amount is an amount sufficient to elicit an anti-human milk fat globule immune response.

Claim 62 (previously presented): The composition of claim 39, wherein the specific immune response comprises production of HMFG-specific antibody.

Claim 63 (previously presented): The composition of claim 39, wherein the specific immune response comprises production of HMFG-specific T cells.

Claim 64 (previously presented): The humanized antibody of claim 35, wherein the specific immune response comprises production of HMFG-specific antibody.

Claim 65 (previously presented): The humanized antibody of claim 35, wherein the specific immune response comprises production of HMFG-specific T cells.

Claim 66 (canceled)

Claim 67 (previously presented): The fusion polypeptide of claim 34, wherein the immunoglobulin constant region is human.

Claim 68 (previously presented): The immunogenic composition of claim 42, further comprising an adjuvant.

Claim 69 (previously presented): The purified antibody of claim 4, said antibody comprising the sequence of SEQ ID NO:2.

Claim 70 (previously presented): The purified antibody of claim 4, said antibody comprising the sequence of SEQ ID NO:4.

Claim 71 (previously presented): The fusion polypeptide of claim 33, wherein the light chain variable region and the heavy chain variable region of antibody 11D10 are joined by a linker polypeptide of about 5 to 20 amino acids.

Claim 72 (previously presented): The humanized antibody of claim 35, wherein the framework regions are human sequences.

Claim 73 (currently amended): A humanized antibody comprising three CDRs from the light chain variable region of 11D10, three CDRs from the heavy chain variable region of 11D10, and framework regions that are human sequences, wherein the humanized antibody is able to stimulate a specific immune response against human milk fat globule (HMFG), wherein the light chain variable region amino acid sequence is contained in an antibody produced by a hybridoma cell line designated ATCC No. HB 12020 ~~or progeny thereof~~, and wherein the heavy chain variable region amino acid sequence is contained in an antibody produced by a hybridoma cell line designated ATCC No. HB 12020 ~~or progeny thereof~~.

Claim 74 (previously presented): A composition comprising the purified antibody of claim 4 and a pharmaceutically acceptable excipient.

Claim 75 (previously presented): A composition according to claim 74, wherein the composition is immunogenic.

Claim 76 (previously presented): A composition according to claim 75, further comprising an adjuvant.

Claim 77 (canceled)

Claim 78 (currently amended): A fusion polypeptide according to claim ~~[[31]]~~ 27, wherein the amino acid sequences of the light chain variable region and the heavy chain variable region are contained in SEQ ID NO:2 and SEQ ID NO:4, respectively.

Claim 79 (previously presented): A fusion polypeptide according to claim 32, wherein the linker polypeptide comprises the amino acid sequence (GGGS)₃ (SEQ ID NO:35).

Claim 80 (previously presented): A humanized antibody according to claim 35, wherein the light chain variable region and the heavy chain variable region are contained in SEQ ID NO:2 and SEQ ID NO:4, respectively.

Claim 81 (previously presented): A composition comprising the humanized antibody of claim 35 and a pharmaceutically acceptable excipient.

Claim 82 (previously presented): A composition according to claim 81, wherein the composition is immunogenic.

Claim 83 (previously presented): A composition according to claim 82 further comprising an adjuvant.

Claim 84 (previously presented): A humanized antibody comprising three CDRs from the light chain variable region of 11D10, three CDRs from the heavy chain variable region of 11D10, and framework regions that are human sequences, wherein the humanized antibody is able to stimulate a specific immune response against human milk fat globule (HMFG), wherein the light chain variable region and the heavy chain variable region are contained in SEQ ID NO:2 and SEQ ID NO:4, respectively.

Claim 85 (previously presented): A composition comprising the humanized antibody of claim 84 and a pharmaceutically acceptable excipient.

Claim 86 (previously presented): A composition according to claim 85, wherein the composition is immunogenic.

Claim 87 (previously presented): A composition according to claim 86, further comprising an adjuvant.

Claim 88 (previously presented): An antibody comprising a light chain variable region amino acid sequence contained in SEQ ID NO:2 and a heavy chain variable region amino acid sequence contained in SEQ ID NO:4.

Claim 89 (previously presented): A composition comprising the antibody of claim 88 and a pharmaceutically acceptable excipient.

Claim 90 (previously presented): A composition according to claim 89, wherein the composition is immunogenic.

Claim 91 (previously presented): A composition according to claim 90, further comprising an adjuvant.

Claim 92 (previously presented): An isolated antibody comprising three CDRs from the light chain variable region of anti-idiotypic antibody 11D10 and three CDRs from the heavy chain variable region of anti-idiotypic antibody 11D10, wherein the CDRs from the light chain variable region are contained in SEQ ID NO:2 and the CDRs from the heavy chain variable region are contained in SEQ ID NO:4.

Claim 93 (previously presented): A composition comprising the antibody of claim 92 and a pharmaceutically acceptable excipient.

Claim 94 (previously presented): A composition according to claim 93, wherein the composition is immunogenic.

Claim 95 (previously presented): A composition according to claim 94, further comprising an adjuvant.

Claim 96 (currently amended): A composition comprising the polypeptide of claim [[77]] 20 and a pharmaceutically acceptable excipient.

Claim 97 (previously presented): A monoclonal anti-idiotypic antibody according to claim 1, comprising the light chain variable region amino acid sequence contained in SEQ ID NO:2 and the heavy chain variable region amino acid sequence contained in SEQ ID NO:4.

Claim 98 (previously presented): A polypeptide comprising an immunoglobulin variable region containing three light chain complementarity determining regions (CDRs) of antibody 11D10, or an immunoglobulin variable region containing three heavy chain CDRs of antibody 11D10, wherein antibody 11D10 is produced by a hybridoma cell line designated ATCC NO. HB 12020.

Claim 99 (previously presented): A composition comprising the polypeptide of claim 98 and a pharmaceutically acceptable excipient.

Claim 100 (previously presented): A polypeptide according to claim 98, comprising an immunoglobulin variable region containing the three light chain CDRs of antibody 11D10.

Claim 101 (previously presented): A polypeptide according to claim 98, comprising an immunoglobulin variable region containing the three heavy chain CDRs of antibody 11D10.

Claim 102 (previously presented): A polypeptide according to claim 98, wherein the light chain variable region is contained in SEQ ID NO:2.

Claim 103 (previously presented): A polypeptide according to claim 98, wherein the heavy chain variable region is contained in SEQ ID NO:4.

Claim 104 (currently amended): A polypeptide ~~according to claim 98~~, comprising an immunoglobulin variable region containing three light chain complementarity determining regions (CDRs) of antibody 11D10 and an immunoglobulin variable region containing three heavy chain CDRs of antibody 11D10, wherein antibody 11D10 is produced by a hybridoma cell line designated ATCC NO. HB 12020, and wherein the light and heavy chain variable region sequences are contained in SEQ ID NO:2 and SEQ ID NO:4, respectively.

Claim 105 (new): A method of eliciting an immune response in an individual with advanced human milk fat globule associated disease comprising the step of administering an effective amount of an antibody according to claim 35 to the individual.

Claim 106 (new): A method of eliciting an immune response in an individual with advanced human milk fat globule associated disease comprising the step of administering an effective amount of an antibody according to claim 73 to the individual.

Claim 107 (new): A method of eliciting an immune response in an individual with advanced human milk fat globule associated disease comprising the step of administering an effective amount of an antibody according to claim 84 to the individual.

Claim 108 (new): A method of eliciting an immune response in an individual with advanced human milk fat globule associated disease comprising the step of administering an effective amount of an antibody according to claim 92 to the individual.

Claim 109 (new): A method of eliciting an immune response in an individual with advanced human milk fat globule associated disease comprising the step of administering an effective amount of a polypeptide according to claim 20 to the individual.

Claim 110 (new): A method of eliciting an immune response in an individual with advanced human milk fat globule associated disease comprising the step of administering an effective amount of a polypeptide according to claim 104 to the individual.

Claim 111 (new): A method for removing a labeled anti-HMFG antibody from an individual who has received a labeled anti-HMFG antibody, comprising administering an antibody according to claim 35 to the individual.

Claim 112 (new): A method for removing a labeled anti-HMFG antibody from an individual who has received a labeled anti-HMFG antibody, comprising administering an antibody according to claim 73 to the individual.

Claim 113 (new): A method for removing a labeled anti-HMFG antibody from an individual who has received a labeled anti-HMFG antibody, comprising administering an antibody according to claim 84 to the individual.

Claim 114 (new): A method for removing a labeled anti-HMFG antibody from an individual who has received a labeled anti-HMFG antibody, comprising administering an antibody according to claim 92 to the individual.

Claim 115 (new): A method for detecting the presence of an anti-HMFG antibody bound to a tumor cell comprising the steps of contacting the tumor cell with an antibody according to claim 35 for a sufficient time to allow binding to the anti-HMFG antibody, and detecting the presence of any antibody which is bound to the anti-HMFG antibody.

Claim 116 (new): A method for detecting the presence of an anti-HMFG antibody bound to a tumor cell comprising the steps of contacting the tumor cell with an antibody according to claim 73 for a sufficient time to allow binding to the anti-HMFG antibody, and detecting the presence of any antibody which is bound to the anti-HMFG antibody.

Claim 117 (new): A method for detecting the presence of an anti-HMFG antibody bound to a tumor cell comprising the steps of contacting the tumor cell with an antibody according to claim 84 for a sufficient time to allow binding to the anti-HMFG antibody, and detecting the presence of any antibody which is bound to the anti-HMFG antibody.

Claim 118 (new): A method for detecting the presence of an anti-HMFG antibody bound to a tumor cell comprising the steps of contacting the tumor cell with an antibody according to claim 92 for a sufficient time to allow binding to the anti-HMFG antibody, and detecting the presence of any antibody which is bound to the anti-HMFG antibody.

Claim 119 (new): A method for detecting an anti-HMFG immunological response in an individual comprising the steps of (a) contacting a biological sample from the individual with an antibody according to claim 35 under conditions that permit formation of a stable complex between said

antibody and an antibody that binds to said antibody; and (b) detecting any stable complexes formed.

Claim 120 (new): A method for detecting an anti-HMFG immunological response in an individual comprising the steps of (a) contacting a biological sample from the individual with an antibody according to claim 73 under conditions that permit formation of a stable complex between said antibody and an antibody that binds to said antibody; and (b) detecting any stable complexes formed.

Claim 121 (new): A method for detecting an anti-HMFG immunological response in an individual comprising the steps of (a) contacting a biological sample from the individual with an antibody according to claim 84 under conditions that permit formation of a stable complex between said antibody and an antibody that binds to said antibody; and (b) detecting any stable complexes formed.

Claim 122 (new): A method for detecting an anti-HMFG immunological response in an individual comprising the steps of (a) contacting a biological sample from the individual with an antibody according to claim 92 under conditions that permit formation of a stable complex between said antibody and an antibody that binds to said antibody; and (b) detecting any stable complexes formed.

Claim 123 (new): A method of detecting in a sample an antibody that binds to monoclonal antibody 11D10 comprising the steps of: (a) contacting antibody from a sample obtained from the individual with the polypeptide of claim 98 under conditions that permit the formation of a stable antigen-antibody complex; and (b) detecting the stable complex formed in step (a), if any.

Claim 124 (new): A method of detecting in a sample an antibody that binds to monoclonal antibody 11D10 comprising the steps of: (a) contacting antibody from a sample obtained from the individual with the polypeptide of claim 104 under conditions that permit the formation of a stable antigen-antibody complex; and (b) detecting the stable complex formed in step (a), if any.